

EFFECTS OF TIME, VOLUME, AND LOCATION ON ARTIFICIAL URINARY SPHINCTER PRESSURE REGULATING BALLOON PRESSURES

Hypothesis / aims of study

A key component of the artificial urinary sphincter (AUS), AMS 800, is the pressure regulating balloon (PRB). Variables affecting the PRB pressure include PRB selected, PRB fill volume, and PRB location. Surgeon practice patterns as to fill volume and location vary widely. Examining how each of these variables contributes to the final PRB pressure in vivo may help guide surgical decision making.

Study design, materials and methods

PRB pressures were prospectively measured in 17 patients undergoing AUS surgery (transperineal cuff placement) using a standard arterial line setup provided by anesthesia. Pressures were measured after filling the PRB with a 4:1 cysto conray II/sterile water mix, ex vivo and in vivo, in virgin PRBs and previously implanted PRBs. In vivo PRBs were placed subrectus, via an abdominal skin incision. Mean ex vivo and in vivo pressures were compared using the unpaired T-test. ANOVA tests were used to compare PRB pressures using different filling volumes in both the in vivo and ex vivo settings. Pressures measured in the previously implanted PRBs were measured and compared to the pressures measured in the virgin PRBs. Mean pressures were compared using the unpaired T-test.

Results

The demographics of the 17 patients were: median age = 71 (range = 38-90), median pre-AUS pads per day = 5 (range = 2-12), and etiology of urinary incontinence (intrinsic sphincter deficiency (ISD) after radical retropubic prostatectomy (RRP) = 12, ISD after radiation therapy for prostate cancer = 1, ISD after both RRP and RT = 2, ISD after pelvic fracture = 1 and spina bifida = 1). In virgin PRBs rated 61-70cmH₂O (N=10) filled with 22mL, the mean pressure was 69.6cmH₂O when measured ex-vivo and 90.6cmH₂O when measured in vivo ($p < 0.001$). See FIGURE. In virgin PRBs rated 61-70cmH₂O (N=10), the mean pressures for the volumes (15, 18, 20, 22, 23, 24, and 25cc) when measured ex-vivo were all found to be similar ($p = 0.969$). The mean pressures for the volumes (20, 22, 25cc) in-vivo, were also similar ($p = 0.503$). When mean in vivo pressure measurements of explanted PRBs (N=7) were compared to virgin PRBs (N=10) at 22cc, they were significantly lower (67.0 vs. 90.6cmH₂O, $p = 0.008$). The median time until PRB explant was 28.3 months. When mean ex-vivo pressure measurements of explanted PRBs (N=9) rated 61-70cmH₂O were compared with virgin PRBs (N=10) at 22cc, they were also found to be significantly lower (53.0 vs. 69.6cm H₂O, $p = 0.001$).

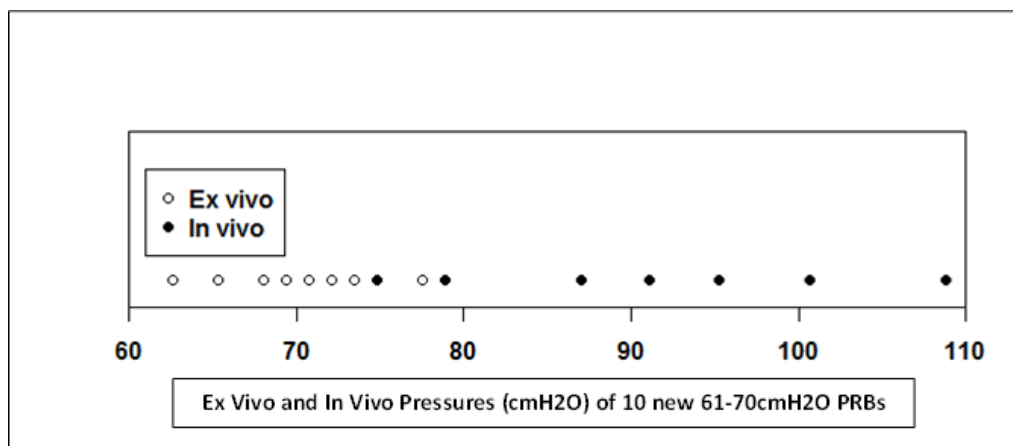
Interpretation of results

When the PRB is placed subrectus, initial pressures are supra-therapeutic, but over time seem to equilibrate to factory rated pressure ranges. Long term effects as to cuff erosion and urethral atrophy are to be determined. Fill volumes ranging from 15-25mL result in the same initial PRB pressures. Thus, differing surgeon preferences for fill volumes seem appropriate in the short term. Old PRBs have lower pressures compared to virgin PRBs, suggesting loss of silicone elasticity over time.

Concluding message

At the time of a PRB exchange, it is prudent to measure the pressure of the old PRB, before replacing with a new higher pressure range PRB.

FIGURE: Ex vivo and in vivo pressures of 10 new 61-70cmH₂O PRBs



Disclosures

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